



29 September 2017

To: Hanoch Sheps Exq.
.....Messner Reeves LLP

From: Cindy S. Orser, PhD

A handwritten signature in black ink, appearing to read "C. Orser", with a long, sweeping horizontal line extending to the right.

RE: Douglas J. Horn and Cindy Harp-Horn v. Medical Marijuana, Dixie Elixirs & Edibles, Red Rice Holdings, LLC and Dixie Botanicals

I have reviewed the following documents as provided:

1. CannLabs Certificate of Analysis: 10.12.Dixie X 500mg Dew Drop (02475533xA9B4D).png
2. CannLabs Certificate of Analysis: 10.16.12.500mg Dew Drop CBD0803MIXE2 (1) (02475534.xA9B4D).pdf
3. CannLabs Certificate of Analysis: 10.16.12CBD1011RD-500mg (02475535xA9B4D).pdf
4. CannLabs Certificate of Analysis: 10.16.12.DD 500 mg CBD0803MIXE2 (02475536xA9B4D).pdf
5. Laboratory report #281201415 from EMSL Analytical Laboratory dated Nov 5, 2012
6. Clinical Reference Lab materials (02343464xA9B4D).pdf
7. Complaint and Jury Demand—Douglas Horn v. Medical Marijuana Inc., Dixie Elixir & Edibles, Red Dice Holdings, LLC, and Dixie Botanicals.
8. Douglas Horn Deposition Transcripts dated 5-9-17 and 5-8-17
7. Written report by expert witness Kenneth Graham, PhD, RPh dated August 29, 2012
8. Photo of Bottle – Plaintiff's Supplemental Disclosure
9. Plaintiff's Expert Disclosure

Background

The conflict between federal and state laws on the medical and recreational use of cannabis products, the lack of consistency among state laws, and the availability of cannabis and CBD products in dispensaries and online has caused significant confusion for researchers, regulators, patients and consumers, particularly with regard to CBD products. It is important to remember

that the events under review in this case happened in 2012, five years ago, under 2012 regulations.

In 2012 under the Controlled Substance Act, it was federally legal to import industrial hemp stalks as they typically contain less than the federal guideline limit for THC in imported industrial hemp, which is 0.3%. It is widely known that those *Cannabis sativa* L. strains being grown for medical marijuana (MMJ) use at the time typically contained 10 to 20% THC. It is also relevant to recognize that cannabis testing was a new testing market in 2012 and there were very few cannabis analytical testing labs with validated testing procedures in place and only in MMJ complicit states. Neither New York or New Jersey fell into that category in 2012.

Brief Sequence of Events

1. Mr. Horn, who had suffered personal injury in a vehicular accident on Feb 24, 2012, made the decision to purchase a high CBD product produced by Dixie Elixir & Edibles and to start using it on or around October 1, 2012 for pain relief. We do not know how much of the product Mr. Horn actually ingested.
2. Dixie Elixirs & Edibles in 2012 imported industrial hemp from outside the US using an FDA import license and extracted the CBD from the plant stalks and made their formulation in Colorado. This Dixie X product line, 500 mg CBD Elixir was commercially launched on September 5, 2012.
3. Mr. Horn's employment required random drug testing. On October 9, 2012, he was randomly selected to supply a urine sample for drug testing. Subsequently on Oct 11, 2012, he learned that he had failed the drug test for a THC metabolite (we are not instructed as to which one) testing at 29 ng/ml with the limit being 15 ng/ml. THC is rapidly metabolized by humans to the equally psychoactive 11- hydroxy-THC (11-OH-THC), and then to the inactive 11-nor-9-carboxy-THC (THC-COOH) metabolite, the normal excreted form.
4. Following being terminated from his job, Mr. Horn purchased an over-the-counter drug test kit and following the kit instructions, collected a urine sample and mailed it to the testing laboratory for analysis. The result was positive for a marijuana metabolite according to Dr. Graham's expert report, but again we do not know which one.
5. Mr. Horn ordered more of the CBD product from Dixie Elixirs & Edibles with the intention to have it tested in New York. The product received was not the identical product which he had taken. The formula was the 100 mg CBD and not the 500 mg CBD Elixir.
6. The 100 mg product was submitted to an EMSL Analytical Laboratory in New Jersey for analysis. The laboratory purportedly identified THC in the product at a concentration of 170 µg/g or 170 ppm but did not report a value for CBD or any other substance in the exemplar product. The 100 mg exemplar product was then purportedly destroyed, providing no

possibility for any other laboratory to test the product to confirm the findings of the EMSL laboratory.

Review of Testing DATA

Within this series of events we have two sources of product testing data to review: 1) the Certificates of Analysis from CannLabs in Denver, Colorado of the Dixie Elixirs & Edibles' 500 mg product; and the Certificate of Analysis of the 100 mg product by EMSL Analytical Laboratory in New Jersey.

Dixie Elixirs & Edibles Products -

CannLabs was an analytical cannabis testing laboratory licensed by the City of Denver and the State of Colorado. CannLabs provided certificates of analysis for three separate representative Dixie Elixirs & Edibles products in the timeframe of October 2012 including one with the same name as purchased by the Plaintiff; *i.e.* 500 mg CBD Dew Drops:

- #1 In CannLabs report identified as 10.16.12.500mg Dew Drop CBD0803MIXE2 (1) (02475534xA9B4D).pdf, the total THC is reported to be **0.05%** for product Dixie X Hemp CBD 500mg Dew Drop.
- #2 In CannLabs report identified as 10.16.12.CBD1011RD-500mg (02475535xA9B4D).pdf, the total THC is reported to be **0.04%** for product CBD1011R&D-500mg.
- #3 In CannLabs report identified as 10.16.12.DD 500 mg CBD0803MIXE2m (02475536xA9B4D).pdf, the total THC is reported to be **0.04%** for product CBD0803MIXE2.

All three of the Dixie Elixirs & Edibles products had an order of magnitude less than the state and federal limit of 0.3% THC; in fact, the same Dixie X Hemp 500 mg Dew Drop contained just 0.05% THC.

No testing results were provided by CannLabs for the Dixie X Hemp 100 mg Dew Drop product.

EMSL Analytical Testing Laboratory –

EMSL Analytical has dozens of accredited analytical testing labs throughout the U.S. focusing on industrial hygiene, environmental and food testing using validated protocols (see Appendix A for full list of tests offered). The EMSL lab report originated from the Corporate office in Cinnaminson NJ. It does not appear that the EMSL Analytical Laboratory network has any accreditation to test cannabis, and therefore no accredited validated procedures.

The EMSL Lab test results was on a different product, the Dixie X Hemp 100 mg Dew Drop, and not the 500 mg product as consumed by the Plaintiff and as tested by CannLabs in Denver. EMSL reported a THC content of 170 µg/g or 0.017% THC which is again an order of magnitude below the federal threshold for a hemp stalk derived product. It is curious that the report did

not also report a CBD value for the product since that was the main active ingredient and would have provided a critical comparative value.

No testing results were provided by the EMSL Lab or by the Plaintiff for the Dixie X Hemp 500 mg Dew Drop product that he actually consumed. In Dr. Graham's report, he extrapolates from the THC content in the 100 mg product to arrive at the THC content in the 500 mg product by multiplying $0.017\% \times 5 = 0.085\%$ which requires making the assumption that the 100 mg was a simple 5-fold dilution of the 500 mg; but since we were not informed as to the volume of the sample, we do not know if this is appropriate or not. Nonetheless, if we take Dr. Graham's value at 0.085%, this is again far below the state and federal threshold for THC at 0.3%.

Urine Drug Test:

Many variables can affect how long THC and its metabolite THC-COOH remain in your system. An edible goes through your gut and then your liver and then makes its way to the kidneys via the blood. Cannabinoid detection times in urine depend upon pharmacological factors (e.g., drug dose, route of administration, duration and frequency of use and individual rates of absorption, metabolism and excretion), and methodological issues including analytes evaluated, matrix, type of hydrolysis, cut-off or threshold used, and sensitivity of the method. The primary psychoactive constituent of cannabis, Δ^9 -tetrahydrocannabinol (THC), is rapidly absorbed during smoking, and due to its high lipophilicity is widely distributed to adipose tissue, liver, lung, and spleen. Body stores of THC increase with increasing frequency and chronicity of cannabis use. THC-COOH has an elimination **half-life** (time it takes to exit the body) of about **4 days on average**. THC is rapidly metabolized to the equally psychoactive 11- hydroxy-THC (11-OH-THC), and to the inactive 11-nor-9-carboxy-THC (THCCOOH) metabolite and its glucuronide and sulfate conjugates.¹ In other words, the actual form of THC that is measured and reported on any report is relevant and in particular if it is found in urine.

Studies involving humans indicate that 80%-90% of the total dose of delta-9-THC (THC) is excreted within 5 days--approximately 20% in urine and 65% in feces²

Expert Summary Findings:

Both myself and Dr. Kenneth Graham are PhDs. Neither of us are MDs or Attorneys. I am an experienced diagnostic, laboratory scientist with most recent direct experience working with cannabis as the Laboratory Director and Chief Science Officer for a cannabis testing laboratory in Las Vegas, NV. All issues associated with this case that deal with legality, regulations,

¹ Huestis, MA.; Smith, ML. Human cannabinoid pharmacokinetics and interpretation of cannabinoid concentrations in biological fluids and tissues. In: Elsohly, M., editor. Marijuana and the Cannabinoids. New York: Humana Press; 2005. p. 205-235.

² Hunt AC, Jones RT (1980) Tolerance and disposition of THC in man. Pharm Exp Ther 215:135-44.

reconciliation of 2012 and 2017 regulations and legal precedent should be left to the Attorneys and the court. Here I will provide my concluding comments on the matters related to the science and analytical lab testing.

1) Without any analytical laboratory test results to review as to what was contained in the actual Dixie Elixir product that was used by Mr. Horn, no one can opine with any degree of scientific confidence that it was the Dixie product used by Mr. Horn that caused him to fail his random DOT urine test of October 9, 2012.

2) CannLabs test results report both a CBD value as well as a THC value which is important as reference for the product, since the main ingredient was CBD. The test results from the EMSL Analytical Lab only reported a THC value which makes comparison to the Colorado lab findings incongruous.

3) There is considerable uncertainty with regards to whether or not the Plaintiffs maintained proper chain-of-custody over the Dixie X Hemp 100 mg Dew Drops product that was tested by the EMSL Lab back in 2012. Even more uncertainty exists for the untampered state of the remaining Dixie X Hemp 500 mg Dew Drop product.

4) Looking at the EMSL website (<https://www.emsl.com/Default.aspx>) for the accredited analytical testing lab in New Jersey where the testing was done, there is no listing for cannabinoid analysis, no method is referenced. Accurate cannabinoid analysis would require having the proper certified reference standards in hand to compare with a previously generated calibration curve using those same reference standards.

5) Because we do not know the amount of Dixie X Hemp 500 mg Dew Drop product Mr. Horn allegedly consumed prior to submitting to a urine drug test, it is impractical to calculate with any degree of scientific certainty a range of expected contaminating THC metabolite in his urine sample based on either the analytical lab testing results reported by CannLabs in Colorado or by the EMSL Lab in New Jersey. Ideally, the remainder of the actual product in question, *ie.* Dixie X Hemp 500 mg Dew Drops, should have been timely tested by a certified cannabis testing lab for both CBD and THC content.

6) Even though Dr. Graham intimates that Mr. Horn could have experienced the conversion of CBD to THC in his stomach, there is no evidence that occurred. Despite Dr. Graham's reference to two publications where a synthetic stomach pH environment was created and molecular rearrangements were noted from CBD to THC, there is *no* evidence from a living, biological system that CBD is chemically transformed to THC in the stomach at any appreciable level and therefore should not be included in any calculations of potential THC metabolites being excreted.

7) The Plaintiffs should have been aware that the labeling on the Dixie X Hemp 500 mg Dew Drop product was not definitive of product content. There was NO certificate of analysis included, only the statement, "this product contains CBD and other cannabinoids." The primary

responsibility in a largely unregulated industry in 2012 rests on the buyer/consumer. The Plaintiffs appeared to be aware of the potential risk of THC contamination and the impact of failing a urine test failure for THC given their line of employment. The Plaintiffs should have had the product tested prior to ingesting knowing their livelihood was at risk.

APPENDIX A.**EMSL Lab Details**

Laboratory Corporate - Cinnaminson, NJ
Address 200 Route 130 North, Cinnaminson, NJ, 08077
Phone 1-800-220-3675, Fax: (856) 786-5974

[Click here for map/directions \(courtesy Google Maps\)](#)

Cinnaminson Laboratory (Corporate Lab) - Laboratory Hours: Monday- Friday 8AM – Midnight, Saturday 8AM - 6PM, Sunday On-Call

Services carried out by this Laboratory (click the Name for details)	Lab Hours
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Asbestos Lab Services	Chain of Custody Form
Consumer Products Testing	Chain of Custody Form
DNA and PCR Testing Laboratory	Chain of Custody Form
Environmental Chemistry Lab Services	Chain of Custody Form
Food and Beverage Testing	Chain of Custody Form
Home Owner Services	Chain of Custody Form
Indoor Air Quality (IAQ) Lab Services	Chain of Custody Form
Industrial Hygiene (IH) Lab Services	Chain of Custody Form
Lead and Metals Lab Services	Chain of Custody Form
Legionella Testing Lab Services	Chain of Custody Form
Materials Testing Lab	Chain of Custody Form
Microbiology Laboratory	Chain of Custody Form
Radiological Testing	Chain of Custody Form

List of Qualifications (click the Certificate for details)	Certificate #	Expires
AIHA-LAP, LLC ELLAP	100194	09/01/2018
AIHA-LAP, LLC EMLAP	100194	09/01/2018
AIHA-LAP, LLC IHLAP	100194	09/01/2018
AIHA ELPAT Participant - Paint Chips, Soil, Dust Wipes, Air	100194	
AIHA EMPAT Participant - Bacteria and Fungi	100194	
AIHA IHPAT Participant - Asbestos, Metals, Silica, Organics, 3M Diffusive Sampler, Formaldehyde and Beryllium	100194	
A2LA Bulk Asbestos and Lead - Cinnaminson	2845.01	05/31/2019
A2LA Chemistry (Food Chemistry/Materials Science) - Cinnaminson	2845.15	05/31/2019
A2LA Food Micro - Cinnaminson	2845.14	05/31/2019
A2LA Material Science/Mechanical - Cinnaminson	2845.16	05/31/2019
NVLAP - Air and Bulk	101048-0	06/30/2018
API - 2011 Food PT certificate	Certificate	
NSF Material Program (Brake Pads) - SAE J2975:2011	CO192670-AL004	02/28/2018
IRSST Recognition - PLM and TEM	See list	
National Radon Proficiency Program	NRPP ID 109000	01/31/2019
National Radon Safety Board - Radon	AL	
National Radon Safety Board - Radon	NRSB-ARL6006	07/30/2019
National Radon Safety Board - Radon Measurement Specialist	NRSB 15SS037	07/30/2019
National Radon Safety Board - Radon Measurement Specialist	NRSB 17SS064	07/30/2019
CDC Elite - Legionella Certificate of Proficiency	Certificate	10/27/2017



FDA - Drug Firm Registration	3003933331	12/31/2017
US Dept of Justice - DEA certificate	RE0419716	08/31/2018
US Dept of Justice - Explosives License/Permit	8-NJ-005-33-0F-00326	06/01/2020
CPSC - Cinnaminson - Metals, Lead, Phthalates	Letter - ID #1140	
EPA - UCMR - Inorganic anions (Chlorate)	Approval letter	
USDA - Soil Permit	P330-17-00019	01/27/2020
Maine - Analyst Individual Certification List	See list	
Vermont - Analyst Individual Certification List (Cinnaminson)	See list	
NC - Microbiology and Inorganic Chemistry	34700	07/31/2017
AL - Cryptosporidium and Giardia	41260	06/30/2018
AL - Asbestos and Lead in Drinking Water	41260	06/30/2018
AL - Radon	NRSB-ARL6006	07/30/2019
AK - Radon	NRSB-ARL6006	07/30/2019
AZ - PLM and TEM	Letter - AZ0955	06/30/2018
AZ - Radon	NRSB-ARL6006	07/30/2019
AR- Radon	NRSB-ARL6006	07/30/2019
CA - Asbestos, Lead and Chemistry for Metals in Drinking Water, Bulk Asbestos, Cryptosporidium and Giardia	1877	06/30/2018
CA - Radon	NRSB-ARL6006	07/30/2019
NJ - Office of Attorney General - CDS	CDS #CA00030200	03/31/2018
CO - PCM, PLM and TEM	AL - 15133	01/30/2018
CO - Asbestos in Drinking Water	Letter	05/31/2018
CO - Lead in Drinking Water	Letter	05/31/2018
CO - Radon	NRSB-ARL6006	07/30/2019
CT - Asbestos, Lead, Micro, Env. Chemistry, Radiochemicals and Cryptosporidium	PH-0270	06/30/2018
CT - Radon	NRSB-ARL6006	07/30/2019
DE - Asbestos, Chemistry, Radon, Micro, Cryptosporidium and Giardia in Drinking Water	Letter	06/30/2018
NY - ELAP - Legionella	10872	04/01/2018
FL - Asbestos, Lead, Chemistry, Microbiology, Cryptosporidium and Giardia	E87975	06/30/2018
FL - Radon	RB2034	07/22/2018
FL - Radon Measurement Specialist	R2451	06/22/2018
GA - Asbestos, Lead, Micro and Cryptosporidium-Giardia	972	06/30/2018
GA - Radon	NRSB-ARL6006	07/30/2019
HI - Bulk Asbestos	L-01-032	07/10/2018
HI - Asbestos in Drinking Water 100.2	Letter	06/30/2018
HI - Radon	NRSB-ARL6006	07/30/2019
ID - Asbestos in Drinking Water	NJ00337	06/30/2018
ID - Radon	NRSB-ARL6006	07/30/2019
IL - Cryptosporidium	1703036	06/30/2018
IL - Radon	RNL2008202	09/30/2019
IN - Lead, Chemistry and Asbestos in Drinking Water	C-NJ-04	06/30/2018
IN - Radon Lab Tester License	RTL00760	12/31/2017
IA - Radon Measurement license	L00032	03/01/2018
KS - Radon	KS-LB-0005	09/30/2019
KS - Radon Measurement Technician	KS-MS-0338	09/30/2019
KY - Radon	NRSB-ARL6006	07/30/2019

LA - Asbestos in Drinking Water	LA170022	12/31/2017
LA - Chemistry, Asbestos in Air, Non-potable Water and Solid Hazardous Waste, Fungi Direct and Cultures	04127	06/30/2018
LA - Radon	NRSB-ARL6006	07/30/2019
ME - Asbestos, Radiochemistry, Env. Lead, E. coli, Crypto and Giardia in DW	2016030	08/16/2018
ME - Radon	SPC202	09/30/2017
ME - Air Asbestos Analysis	LA-0038	10/31/2018
ME - Bulk Asbestos Analysis	LB-0039	10/31/2018
MD - Asbestos, Chemistry and Radiochemistry in Drinking Water	331	06/30/2018
MD - Radon	NRSB-ARL6006	07/30/2019
MA - PCM, PLM and TEM	AA000056	09/28/2018
MA - Asbestos, Lead and Radiochemistry in Drinking Water	M-NJ337	06/30/2018
MA - Cryptosporidium	See letter	06/30/2018
MA - Radon	NRSB-ARL6006	07/30/2019
MI - Asbestos, Micro and Cryptosporidium in Drinking Water	9970	06/30/2018
MI - Radon	NRSB-ARL6006	07/30/2019
MN - Radon	NRSB-ARL6006	07/30/2019
MS - Asbestos in Drinking Water	Letter	06/30/2018
MS - Radon	NRSB-ARL6006	07/30/2019
MO - Radon	NRSB-ARL6006	07/30/2019
MT - Asbestos and Chemistry in Drinking Water	CERT0016	01/01/2018
MT - Radon	NRSB-ARL6006	07/30/2019
NE - Micro and Asbestos in Drinking Water	NE-OS-19-08	06/30/2018
NE - Radon Measurement Specialist	342	03/31/2019
NE - Radon Measurement License	RMB-1083	03/31/2019
NV - Asbestos in DW and Bulk Asbestos (PLM)	NJ003372018-1	07/31/2018
NV - Radon	NRSB-ARL6006	07/30/2019
NH - Asbestos and Radiochemistry in Drinking Water	2988	10/22/2017
NH - Radon	NRSB-ARL6006	07/30/2019
NJ - NELAP - Asbestos, Chemistry, Gravimetric, TO-15, Microbiology, Radon, Cryptosporidium and Giardia	03036	06/30/2018
NM - Radon	NRSB-ARL6006	07/30/2019
NY - ELAP - Asbestos, Metals, TCLP, Lead, Chemistry, PCB, Radon, Total Coliform, TO-15, TO-17 and TO-10A	10872	04/01/2018
NJ - Radon Measurement License	MEB92525	04/24/2018
NJ - DWLD OSC - Permit to Store Explosives	12510	03/31/2018
NC - Asbestos in Drinking Water and Cryptosporidium	34700	07/31/2018
NC - Radon	NRSB-ARL6006	07/30/2019
ND - Radon	NRSB-ARL6006	07/30/2019
ND - TCLP, Metals and Pesticides	R-208	06/30/2018
OH - Cryptosporidium	Letter	06/30/2018
OH - Lead in Paint Chips, Wipes, Soil and Air	E10002	06/02/2018
OH - Radon	RL39	07/11/2019
OH - Ohio VAP - Asbestos and VOC/TO-15	CL105	04/19/2018
OK - Radon	NRSB-ARL6006	07/30/2019
OR - Radon	NRSB-ARL6006	07/30/2019
PA - Radon	2573	03/13/2019
PA - Radon Analyst Certification	3111	09/29/2019
PA - Asbestos, Chemistry, Radon, Micro and Cryptosporidium	014-001	11/30/2017
PA - Philadelphia - PCM, PLM and TEM	ALL-137	04/30/2018

NJ - Radioactive Materials License	RAD150001 - 535776	08/31/2020
RI - PCM, PLM and TEM	AAL-075	04/30/2018
RI - Asbestos, Chemistry and Radiochemistry in DW	LAO00318	12/30/2017
SC - Asbestos in Drinking Water	94017001	06/30/2018
SC - Cryptosporidium	94017002	06/30/2018
SC - Radon	NRSB-ARL6006	07/30/2019
SD - Asbestos in Drinking Water	Letter	06/30/2018
SD - Radon	NRSB-ARL6006	07/30/2019
TN - Asbestos in Drinking Water	TN02856	06/30/2018
TN - Radon	NRSB-ARL6006	07/30/2019
TX - Asbestos, Lead, Chemistry and Micro in Drinking Water	T104704177-17-13	08/31/2018
TX - PCM, PLM and TEM	300161	11/02/2017
TX - Mold	LAB1002	01/08/2018
TX - Radon	NRSB-ARL6006	07/30/2019
UT - Radon	NRSB-ARL6006	07/30/2019
VT - PCM, PLM and TEM	AL818603	07/29/2018
VT - Asbestos, Metals, Radon in Drinking Water	VT-04006	10/03/2018
VT - Lead	LL379642	07/26/2018
VA - PCM, PLM and TEM	3333 000075	02/28/2018
VA - Radon	NRSB-ARL6006	07/30/2019
VA - NELAC - Asbestos, Lead, Cryptosporidium, Organics, Metals and Inorganics	460184	09/14/2018
WA - Asbestos (PCM, PLM and TEM), Lead, Chemistry, Methamphetamine and PCB in Drinking and Waste Water.	C922	07/14/2018
WA - Radon	NRSB-ARL6006	07/30/2019
WV - Air and Bulk Asbestos	LT000571	07/31/2018
WV - Cryptosporidium	9967 M	12/31/2017
WV - Radon	RL000197	09/30/2018
WI - Radon	NRSB-ARL6006	07/30/2019
WY - Radon	NRSB-ARL6006	07/30/2019
WI - Cinnaminson	121065	04/30/2018

<https://www.emsl.com/Default.aspx>